UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/584,486	04/09/2007	Darrell Sleep	11069.204-US	3066

25908 7590 08/20/2010

NOVOZYMES NORTH AMERICA, INC.
500 FIFTH AVENUE
SUITE 1600
NEW YORK, NY 10110

EXAMINER	
KETTER, JAMES S	

ART UNIT	PAPER NUMBER
1636	

NOTIFICATION DATE	DELIVERY MODE
08/20/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

Patents-US-NY@novozymes.com

Office Action Summary	Application No.	Applicant(s)	
	10/584,486	SLEEP ET AL.	
	Examiner	Art Unit	
	James S. Ketter	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 May 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-45,47 and 64-66* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-29,34-42 and 66* is/are rejected.

7)☒ Claim(s) *30-33,43-45,47,64 and 65* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *22 June 2006 and 20 September 2007* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

In view of a newly discovered reference, the finality of the previous Office Action is hereby **Withdrawn**, and new grounds of rejection is presented below. The delay in discovering and presenting this reference is regretted.

Claims 30-33, 43-45, 47, 64 and 65 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-22, 34-42 and 66 are rejected under 35 U.S.C. 102(b) as being anticipated by Jayaram et al. (U, newly cited).

Claim 1 is drawn to a 2 μm-family plasmid comprising a polynucleotide sequence insertion, deletion and/or substitution between a first base after a last functional codon of at least one of either an REP 2 gene or an FLP gene and a last base before an FRT site in an inverted repeat adjacent to said gene. Claim 2 specifies within claim 1 that, other than the polynucleotide sequence insertion, deletion and/or substitution, the FLP gene and/or the REP2 gene has the sequence of an FLP gene and/or an REP2 gene from a naturally occurring 2 μm- family plasmid. Claim 3 specifies within claim 1 that the plasmid comprises pSR1, pSB3 or pSB4 from

Zygosaccharomyces rouxii, pSB 1 from Zygosaccharomyces bailli, pSB2 from Zygosaccharomyces bailli, pSM1 from Zygosaccharomyces fermentati, pKD1 from Kluyverornyces drosophilarum, pPM1 from Pichia membranaefaciens, or the 2 μm plasmid from Saccharomyces cerevisiae. Claim 4 specifies within claim 2 that the sequence of the inverted repeat adjacent to said FLP and/or REP2 gene is from the sequence of the corresponding inverted repeat in the same naturally occurring 2pm-family plasmid as the sequence from which the gene is from. Claim 5 specifies within claim 2 that the naturally occurring 2 μm-family plasmid is the 2 μm plasmid as from Saccharomyces cerevisiae. Claim 6 specifies within claim 5 that the polynucleotide sequence insertion, deletion and/or substitution occurs at a position between a first base of codon 59 of the REP2 gene and the last base before the FRT site in the adjacent inverted repeat. Claim 7 specifies within claim 5 that, other than the polynucleotide sequence insertion, deletion and/or substitution, the sequence of the REP2 gene and the adjacent inverted repeat comprises the nucleotides of SEQ ID NO: 1, or a nucleotide sequence 95% identical to SEQ ID NO:1. Claim 8 specifies within claim 1 that the polynucleotide sequence insertion, deletion and/or substitution occurs at a position between a first base of the inverted repeat and a last base before the FRT site. Claim 9 specifies within claim 1 that the polynucleotide sequence insertion, deletion and/or substitution occurs between a first base after the end of the REP2 coding sequence and the last base before the FRT site. Claim 10 specifies within claim 1 that, other than the polynucleotide sequence insertion, deletion and/or substitution, the inverted repeat that follows the REP2 coding sequence has a sequence from a corresponding region of the 2pm plasmid from Saccharomyces cerevisiae. Claim 11 specifies within claim 5 that the polynucleotide sequence insertion, deletion and/or substitution occurs at a position between a

first base of codon 344 of the FLP gene and the last base before the FRT site in the adjacent inverted repeat. Claim 12 specifies within claim 5 that, other than the polynucleotide sequence insertion, deletion and/or substitution, the sequence of the FLP coding sequence and the adjacent inverted repeat comprises the nucleotides of SEQ ID NO: 2, or a nucleotide sequence 95% identical to SEQ ID NO:2. Claim 13 specifies within claim 11 that the polynucleotide sequence insertion, deletion and/or substitution occurs at a position between a first base of the inverted repeat and the last base before the FRT site. Claim 14 specifies within claim 13 that the polynucleotide sequence insertion, deletion and/or substitution occurs at a position between a first base after the end of the FLP coding sequence and the last base before the FRT site. Claim 15 specifies within claim 14 that the polynucleotide sequence insertion, deletion and/or substitution occurs at a first base after the end of the FLP coding sequence. Claim 16 specifies within claim 11 that, other than the polynucleotide sequence insertion, deletion and/or substitution, the inverted repeat that follows the FLP gene has a sequence from a corresponding region of the 2 μm plasmid from Saccharomyces cerevisiae. Claim 17 specifies within claim 1 that the plasmid comprises polynucleotide sequence insertions, deletions and/or substitutions between a first base after the last functional codons of both of the REP2 gene and the FLP gone and a last base before the FRT sites in the inverted repeats adjacent to each of said genes, which polynucleotide sequence insertions, deletions and/or substitutions can be the same or different. Claim 18 specifies within claim 1 that the plasmid comprises a polynucleotide sequence insertion, deletion and/or substitution which is not between the first base and the last base. Claim 19 specifies within Claim 18 that the polynucleotide sequence insertion, deletion and/or substitution occurs within an untranscribed region around an ARS sequence. Claim 20 specifies

within claim 1 that the, or at least one, polynucleotide sequence insertion, deletion and/or substitution is a polynucleotide sequence insertion. Claim 21 specifies within claim 20 that the polynucleotide sequence insertion encodes an open reading frame. Claim 22 specifies within claim 21 that the open reading frame encodes a non-2 μm-family plasmid protein. Claim 34 specifies within claim 1 that the method comprises: (a) providing a plasmid comprising the sequence of a REP 2 gene and the inverted repeat that follows the REP2 gene, or a FLP gene and the inverted repeat that follows the FLP gene, in each case the inverted repeat comprising an FRT site; or (b) providing a polynucleotide sequence and inserting the polynucleotide sequence into the plasmid of Claim 1 between the first base after the last functional codon of at least one of either the REP2 gene or the FLP gene and the last base before the FRT site in an inverted repeat adjacent to the gene; and/or (c) deleting some or all of the nucleotide bases between the first base after the last functional codon of at least one of either the REP2 gene or the FLP gene and the last base before the FRT site in an inverted repeat adjacent to the gene of Claim 1; and/or (d) substituting some or all of the nucleotide bases between the first base after the last functional codon of at least one of either the REP2 gene or the FLP gene and the last base before the FRT site in an inverted repeat adjacent to the gene with alternative nucleotide bases. Claim 35 is drawn to a plasmid obtainable by the method of Claim 34. Claim 36 is drawn to a host cell comprising a plasmid as defined by Claim 1. Claim 37 specifies within claim 36 that the cell is a yeast cell. Claim 38 specifies within claim 36 that the plasmid is stable as a multicopy plasmid. Claim 39 specifies within claim 38 that the plasmid comprises a polynucleotide sequence insertion, deletion and/or substitution between a first base after a last functional codon of at least one of either an REP 2 gene or an FLP gene and a last base before an FRT site in an inverted

repeat adjacent to said gene. Claim 40 specifies within claim 38 that, if the plasmid contains, or is modified to contain, a selectable marker then stability, as measured by the loss of the marker, is at least 1%, 2%, 3%, 4%, 5%, 10%, 15%, 20%, 25%, 30%, 40%, 50%, 60%, 70%, 75%, 80%, 85%, 90%, 95%, 96%, 97%, 98%, 99%, 99.9% or 100% after 5 generations. Claim 41 is drawn to a method of producing a protein comprising the steps of- (a) providing a plasmid as defined by Claim 1; (b) providing a suitable host cell; (c) transforming the host cell with the plasmid; and (d) culturing the transformed host cell in a culture medium; (e) thereby to produce the protein. Claim 42 is drawn to a method of producing a protein comprising the steps of providing a host cell as defined by Claim 36 which host cell comprises a plasmid comprising a polynucleotide sequence insertion, deletion and/or substitution between the first base after the last functional codon of at least one of either a REP2 gene or an FLP gene and the last base before the FRT site in an inverted repeat adjacent to said gene as and culturing the host cell in a culture medium thereby to produce the protein. Claim 66 specifies within claim 1 that the plasmid comprises a heterologous sequence encoding a protein of interest.

Jayaram et al. teaches, e.g., at Figure 3, 2 μm circle molecules with Tn5 insertions, particularly 42 and 189, which occur within the inverted repeat region. Tn5 encodes its transposase. The insert sites are before the FRT site, and are just downstream of the ends of the FLP and REP2 genes, respectively.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 23-29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 23, and therefore claims 24-29 which depend therefrom, the term "e.g.," renders the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James S. Ketter whose telephone number is 571-272-0770. The examiner can normally be reached on Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JSK
17 August 2010

/James S. Ketter/
Primary Examiner, Art Unit 1636